

CLAIMS

1. A method for the preparation of crystalline dexloxiglumide by crystallization of the crude product from solvent, characterized in that isopropyl ether is used as solvent.
2. A method according to Claim 1, characterized in that a ratio of one part by weight of crude product with a quantity of between 1.5 and 3 parts by volume of isopropyl ether solvent is used.
3. A method according to Claim 1 or Claim 2, characterized in that the crystallization step is performed by adding a seeding of microcrystalline dexloxiglumide having an average particle size ( $D_{50}$ )  $\leq 20 \mu\text{m}$  to a supersaturated solution of crude dexloxiglumide.
4. A method according to Claim 3, characterized in that the seeding is added to a supersaturated solution of crude dexloxiglumide which is kept at a temperature of between 35 and 40°C, in a ratio of one part of seeding material to 40-200 parts of crude product.
5. A method according to Claim 3 or Claim 4, characterized in that, after the addition of the seeding material, the reaction mass is stirred at a temperature of between 34 and 38°C, preferably 36°C, for a period of between 2 and 8 h, preferably 6 h, and the temperature of the reaction mass is then reduced slowly, with stirring, to  $10 \pm 5^\circ\text{C}$  over a period of between 6 and 10 h, preferably 8 h, and in which the crystallized solid is recovered by filtration.

6. Dexloxiglumide in crystalline particle form having a percentage (by volume) of less than 15% of fine particles having dimensions less than 10  $\mu\text{m}$ , and an average particle size value ( $D_{50}$ ) of between 50 and 130  $\mu\text{m}$ .

7. Dexloxiglumide according to Claim 6 in crystalline particle form, having an average particle size value ( $D_{50}$ ) of between 80 and 100  $\mu\text{m}$ .

8. Dexloxiglumide in crystalline particle form according to Claim 6 or Claim 7, having a particle-size distribution with a span index of less than 2.5.

9. Dexloxiglumide according to any one of Claims 6 to 8, obtainable by means of a method of preparation by crystallization according to any one of Claims 1 to 5.

10. A pharmaceutical composition for oral use comprising, as active substance, dexloxiglumide according to any one of Claims 6 to 9.

11. A pharmaceutical composition according to Claim 10, comprising dexloxiglumide in a quantity of between 50 and 500 mg and optional pharmaceutically acceptable vehicles.

12. A pharmaceutical composition according to Claim 11, comprising, as inactive ingredients, pharmaceutically acceptable vehicles selected from diluents, disaggregants, lubricants, flow-promoting agents, and mixtures thereof.

13. A pharmaceutical composition according to Claim 12, comprising, as vehicles, substances selected from the group which consists of starch, microcrystalline cellulose, sodium

glycolate, talc, magnesium stearate, silicon dioxide, and mixtures thereof.

14. A pharmaceutical composition for oral use according to any one of Claims 10 to 12 for use in the treatment of diseases of the digestive tract, particularly of irritable colon syndrome, non-ulcerative dyspepsia, biliary colic and dyskinesia, gastro-oesophageal reflux, pancreatitis, and gastrointestinal motility disorders.